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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/713,544	11/14/2003	R. Steven Davidson	57778.8001.US01	7965

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EXAMINER	
EBRAHIM, NABILA G	
ART UNIT	PAPER NUMBER
1618	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/713,544	DAVIDSON, R. STEVEN	
	Examiner	Art Unit	
	NABILA G. EBRAHIM	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12,17-24 and 27-32* is/are pending in the application.

4a) Of the above claim(s) *1-12 and 19-24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17,18,25 and 27-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/12/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The receipt of claim' amendment and Information Disclosure Statement dated 11/12/2009 is acknowledged.

Status of Claims:

Claims 1-12, 17-24 and 27-32 are pending in the application.

Claims 17, 18, 25 and 27-32 are under current examination.

Claims 1-12, and 19-24 were withdrawn from consideration due to restriction requirements.

Priority

Applicant claims priority to provisional applications 60/426598 and 60/497186. Solely, the latter application teaches the powder matrix recited in the instant claims. Thus, the priority date of this claim will have priority to 08/22/2003.

In view of the amendments to the claims and the new claims added to the list of claims, this new ground of rejection is necessitated.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 17, 27, 28 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably

convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new Matter rejection

Claim 17 recites "benzocaine greater than 0% but less than about 12%" and "pectin greater than 0% but less than about 60%". The instant claims now recite limitations which were not clearly disclosed in the specification as-filed and now change the scope of the instant disclosure as-filed. Such limitations recited in the present claims, introduce new concepts and thus violate the written description requirement of the first paragraph of 35 U.S.C. §112.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to identify sufficient written support in the original specification for the "limitations" indicated above.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 11-12, 17-24 and 27-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Brown WO 98/20861 in view of Corriveau et al. US 20040043134 (Corriveau) in view of Leung et al. US 7025983 (Leung) and further in view of Dettmar et al US 6391294 (Dettmar).

Brown discloses solid dosage form in the form of a sheet or film (page 1, lines 11 and 19); the dosage form is coated with a dry powder coating (page 5, lines 27 and 28; claim 3). The film may be designated to treat cough (page 29, line 30), it is known that TheraFlu® Flu and Cold Medicine for Sore Throat Maximum Strength contains

(Chlorpheniramine Maleate, Acetaminophen, and Pseudoephedrine Hydrochloride). The film and the coating both contain biologically active pharmaceutical material (pages 4 and 5).

Brown teaches films coated with powder matrix to treat cough. The reference is deficient in teaching the ingredients recited in claims 17 and 18.

Corriveau teaches a rolled edible thin film made of a thin film layer rapidly **dissolving in less than 15 seconds** [0065]. The film contains water 9.5% of the finished wt soluble film-former such as carrageenan, pectins, and carboxymethyl cellulose -among others- alone or in any combination in an amount of 5 % to about 60 % by dry weight or 20% to about 40% by dry weight. The film comprise cherry 15% of the finished wt., acsulfame K in an amount of 1.0% of the finished wt., sucralose 1.45% of the finished wt., lecithin 0.5% of the finished wt., glycerin 5% of the finished wt., sodium benzoate [0095], no amount disclosed., menthol 6% of the finished wt., carboxymethyl cellulose 5% of the finished wt., pectin 4% of the finished wt. [see paragraph 0102 and claims]. The reference also teaches emulsifiers such as polyethylene sorbitan esters which is a generic disclosure of polysorbate 80.

These amounts read on both claims 17 and 18 except for sodium benzoate which is a conventional preservative and well known in the art. Deciding the amount of such ingredient would be within the purview of a person having ordinary skill in the art.

Regarding new claims 31 and 32 which recite that the powder coating is applied to the two sides of the film, Brown discloses an accurate method of limiting the coated area, this is a procedure that was difficult to achieve. Therefore, it would be much easier

to a person having ordinary skill in the art to coat the whole substrate on the two sides. Further, Corriveau teaches coating the film using coating techniques such as spraying, dipping, knife over plate, roll over roll, and reverse roll. Such techniques are known to achieve 2 sides coating. Thus, it would be within the abilities of a person having ordinary skill in the art to decide how expanded the coating should be and match one suitable technique to make it.

It would have been obvious to a person having ordinary skill in the art to use the ingredients taught by Corriveau to accelerate the dissolution of the film disclosed by Brown and facilitate using the dosage form to the patients.

Corriveau teaches polyethylene sorbitan esters. However, the reference does not specify polysorbate 80.

Leung teaches fast dissolving orally consumable films which are used to deliver breath deodorizing agents, antimicrobial agents and salivary stimulants to the oral cavity. The films can also be used to deliver pharmaceutically active agents [0001] such as antitussives, expectorants, decongestants, antihistamines, [0102-0106], note that all these drugs are known to treat pharyngitis and cough. It is also noted that the mouth bad odor is a symptom associated with pharyngitis. Consequently it would improve a condition of pharyngitis. The film also comprises menthol (abstract) and a film-forming material such as pectin [0033] in an amount from about 0.01 to about 99 wt %, preferably about 30 to about 80 wt %. Since other ingredients are recited in instant claim 17 in an amount that is possible to be 0%, then these ingredients are not limiting the claims. Pectin is used in amounts ranging from about 45 to about 70 wt % of the film

and even more preferably from about 60 to about 65 wt % of the film [0033]. Further, Leung teaches menthol which can be added from about 0.01 to about 15 wt % of the composition, preferably about 2.0 to about 10 wt % and even more preferably from about 3 to about 9 wt % of the film [0031]. The film may contain water [0034] in an amount of about 0.1 to about 8 wt % (claim 10), an amount of about 0.1 to about 15wt % of at least one flavoring agent (claim 10) which may be cherry [0052]. Leung also teaches acesulfame-K (a sweetening agent), the free acid form of saccharin [0047] in an amount of about 0.1 to about 15 wt % (claim 10). Carrageenan is taught in amounts ranging from about 0 to about 10 wt %, preferably about 0.1 to about 2 wt % of the film [0042]. Sucralose is also disclosed as a sweetener agent. Leung teaches the use of lecithin, in amounts ranging from about 0.01 to about 0.7 wt % of the film [0042]. Examples 2-4 use glycerin [0148] in an amount of 2% (table 2). Leung teaches that a preservative may be added in amounts from about 0.01 wt % to about 1 wt % of the film and that the preferred preservatives include sodium benzoate [0121]. Polysorbate 80 is also used in an amount between 0.355 to 0.4 % (table 2) and a preferred thickening agents include carboxyl methylcellulose, and the like, in amounts ranging from about 0.01 to about 5 wt % [0043].

Thus, it would have been obvious to a person having ordinary skill in the art to include polysorbate in the film compositions disclosed by brown and Corriveau, first because of the similarity between the compounds disclosed by Corriveau and Leung, second, because Corriveau teaches that polysorbate 80 is a preferred surfactant (col. 5, lines 65+).

Regarding the limitation in claims 17 and 18 which recites that the pectin may be replaced with one or more of the groups consisting of gelatin, maltodexrin, modified food starch, TiO2, and acacia gum, it is noted that Leung recognized that some of these film-formers such as gelatin, high amylose starch and acacia gum are all usable as film-formers in the invention, accordingly, it would have been obvious to a person of ordinary skill in the art to replace one of these substances with the other or replace some of the amount used with another substance to advance a specific property in the film produced such as rigidity, elasticity, thickness or thinning, etc.

Note that the references, disclose the combination of water, cherry flavor, carrageenan, acesulfame potassium, sucralose, lecithin, glycerin, sodium benzoate, polysorbate, menthol, carboxymethyl cellulose, pectin and vitamin E in amounts that overlap or differ in a small amount. It has been held that where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. See In re Aller, 220 F.2d 454 105 USPQ 233, 235 (CCPA 1955). Furthermore, the claims differ from the reference by reciting various concentrations of the active ingredients. However, the preparation of various pharmaceutical compositions having various amounts of the active is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. See In re Russell, 439 F.2d 1228 169 USPQ 426 (CCPA 1971).

None of the references teaches benzocaine in the coating and in the film material.

Dettmar teaches pharmaceutically acceptable bio-adhesive coating, film or gel formed in situ at a body surface by the reaction of two components supplied either as separate aqueous solutions or in a single non-aqueous formulation, which can be a liquid suspension tablet, capsule or powder (abstract).

The reference discloses that one of the components may be selected from any anionic polymers that are water-soluble or dispersible and that will form a coating, gel or **film** in the presence of component b). Preferred anionic polymers include water-soluble salts of hyaluronic acid, water-soluble salts of alginic acids (e.g. sodium alginate, potassium alginate), water-soluble or dispersible salts of polyacrylic acids (e.g. sodium carbomers), xanthan gum, acacia, pectins, sterculia, carrageenan salts, polylactic acid and water-soluble cellulose derivatives (e.g. sodium carboxymethyl cellulose). Most preferred anionic polymers for use in the present invention are water soluble or dispersible carbomer salts, water-soluble salts of alginic acids and water-soluble salts of cellulose derivatives (col. 2, lines 5+). It is noted that this composition reads on the powder matrix recited in the instant claims because the underlined compounds are disclosed in the instant application as possible ingredients of the "powder matrix coating". Therefore, it is the position of the Examiner that since Dettmar teaches the same coating mixtures, then the reference teaches the “powder matrix” disclosed in the instant claims even if it is called "coating". Dettmar also teaches that **benzocaine** and lignocaine is included in the composition to treat **sore throat** (example 19 and claim 14). It is noted that pharyngitis is one of the symptoms manifested by sore throat and that numbness is an expected effect of benzocaine which is a well know local

anesthetic. It is also noted that Dettmar teaches solutions that turns into a film when placed on the mucous membrane to treat such condition.

Thus, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to combine the ingredients in the amounts taught by Corriveau and/or Leung to the powder matrix coated film disclosed by Brown to treat pharyngitis and since the three references teach a film or thin sheet having pharmaceuticals that improves cough and pharyngitis. The person of ordinary skill would be motivated by the fact that film dosage forms are easier in administration and can work locally and systemically on a patient in need of the drug and the artisan would have reasonable expectation of success of achieving the needed effect of such drugs.

Response to Arguments

Applicant's arguments filed 11/12/2009 have been fully considered but they are not persuasive. Applicant argues that:

Brow discloses incomplete coating while new claims recite 2 sided coating.

This was not found persuasive because Brown's disclosure is to apply the more difficult process of limiting the coating to a specific area. However, the regular two sided coating is conventional and well known in the art. In addition, new reference Corriveau teaches a conventional coating on a film which is usually 2 sided.

Applicant argues that Brown does not teach "providing an edible film, wherein the edible film consist essentially of a film layer and a powder matrix coating" as claimed. One skilled in the art would not modify the two coatings and substrate of Brown in the claimed manner in view of Brown's teaching to the contrary.

Applicant claims edible film consisting essentially of a film layer and a powder matrix coating, it is noted that the transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention. In re Herz, 537 F.2d 549, 551-52,190 USPQ 461, 463 (CCPA 1976) (emphasis in original). If an applicant contends that additional steps or materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. In re De Lajarte, 337 F.2d870, 143 USPQ 256 (CCPA 1964). See also Ex parte Hoffman, 12 USPQ2d 1061,1063-64 (Bd. Pat. App. & Inter. 1989. Thus, the recitation does not exclude Brown since the reference teaches a film layer and powder coating. A person having ordinary skill in the art would follow Brown's disclosure of having film substrate and powder coating.

Applicant's arguments with respect to Acharya renders moot in view of withdrawing the reference. Further, the arguments with regard to the dissolution time, and the disclosure of benzocaine renders moot in view of the new grounds of rejection.

Pertinent Prior Art

The reference which is considered pertinent to the subject matter of this application but was not relied upon is FEDORENKO et al. RU 2065302 C1 (abstract only).

The reference teaches Analgesic composition. "Ferrokain" is used for local application. The mixture contains (in wt. %): novocaine 0.75-3.75 and highly dispersed

ferromagnetic iron powder coated with crosslinked polyacrylamide 96.25-99.25. External magnetic field is used to position the composition where it is needed within the organism, and to hold it there in order to prolong its analgesic action.

USE - The composition is used in medicine.

ADVANTAGE - More efficient application of local analgesic is achieved.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NABILA G. EBRAHIM whose telephone number is (571)272-8151. The examiner can normally be reached on 9:00AM - 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nabila G Ebrahim/
Examiner, Art Unit 1618

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618